



PATENT
Customer No. 22,852
Attorney Docket No. 08790.0012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
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John P. DONOGHUE et al.) Group Art Unit: 3762
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Application No. 10/798,919) Examiner: Kahelin, Michael W.
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Filed: March 12, 2004) Confirmation No.: 7030
)
For: NEUROLOGICAL EVENT)
MONITORING AND THERAPY)
SYSTEMS AND RELATED)
METHODS)

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants request a pre-appeal brief review of the March 28, 2006, Office Action. This Request addresses the rejections of claims 1 and 64, the sole examined (non-withdrawn) independent claims. These claims relate to a system for predicting occurrence of a neurological event and a method for treating a neurological event, respectively. They include comparing detected signals with a target signal. The target signal includes one or more previously detected signals indicative of activity that precedes a neurological event. Claims 1 and 64 stand rejected first under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Publication No. 2003/0004428 to Pless and second under 35 U.S.C. § 103(a) as being unpatentable over Pless in view of U.S. Patent No. 4,974,602 to Abraham-Fuchs.

I. The Claims Are Not Anticipated By Pless

To establish a case of anticipation, every claim element must be found, either expressly or inherently, in a single prior art reference. Neither Pless nor Fischell (which Pless incorporates by reference) discloses at least the elements of comparing detected signals with a target signal, wherein the target signal includes one or more previously detected signals indicative of activity that precedes a neurological event.

Indeed, the Examiner admits as much by stating that “Pless discloses the essential features of the claimed invention *except for explicitly specifying that the target signals be previously detected.*” (See Office Action at page 7; emphasis added).

Nonetheless, earlier in the final Office Action, the Examiner states “the event detection algorithm incorporated by Pless and disclosed by Fischell comprises storing a target signal indicative of activity preceding a neurological event, in the form of a threshold.” (Id. at 3.) The Examiner further asserts that the threshold *inherently* includes a previously detected signal by stating that the “Examiner is interpreting a threshold as a constant level signal that is inherently set by some previous signal.” (Id.)

“To establish inherency, [however], the extrinsic evidence ‘must make clear that missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.’” *In re Robertson*, 169 F.3d 743, 745 (Fed Cir. 1999)(citations omitted)(emphasis added). Here, the Fischell threshold is not *necessarily* a previously detected signal. In fact, Fischell simply refers to the threshold as a preset level programmed to minimize the chance of missing a neurological event. (Fischell at 19:37-43 and 20:19-26). These disclosures, with Fischell’s failure to suggest how to establish the threshold value, indicate that the Fischell threshold does not *necessarily* include a previously detected signal.

In response to these arguments, the Examiner once again admits that “Pless and Fischell do not explicitly disclose that the target signal includes one or more previously detected signals.” (Advisory Action at 2.) The Examiner, however, asserts that “Fischell does implicitly specify that the target signal includes a previously detected signal at column 20, line 19.” (Id.) The cited paragraph relied on by the Examiner simply teaches that the thresholds “will typically be programmed to minimize the chance of missing a ‘real’ neurological event even though this could result in the occasional false positive identification of an event.” Presetting a threshold to achieve false positives, however, does not *necessarily* imply that the threshold is a “previously detected signal indicative of the activity that precedes the neurological event,” as claimed. Instead, the threshold certainly could be selected as an arbitrarily low value to ensure a sufficient number of false positives.

The Examiner further asserts that “Fischell also discloses a time-domain analysis of electrical activity wherein the target signal (in this case time delay) is based on diagnostic testing of the patient (col. 24, line 6.)” (Advisory Action at 2). However, the time delay disclosed by Fischell refers generically to “the principle that the signals arriving at the electrodes...from an epileptic focus will always do so with the same time delay for each electrode.” (See Fischell at 15:49-52.) In this case, time delay is essentially a correction factor which compensates for the time required for an electrical signal, originating at the epileptic focus, to reach a particular electrode, located some distance from the focus. Fischell makes no mention that this time delay, which the Examiner relies on as teaching Applicants’ claimed target signal, is indicative of activity that precedes a neurological event. In fact, Fischell states that “values for these time delays could be based on measured delays of EEG signals received from an epileptic

focus.” (Id. at 24:6-9.) EEG signal delays are not a “previously detected signal indicative of the activity that precedes the neurological event.”

For these reasons, Pless and Fischell fail to disclose every element of independent claims 1 and 64, and the Section 102(b) rejection should be withdrawn.

II. The Combination of References Does Not Include Every Claim Element

Following the Pless anticipation rejection with an obviousness rejection combining Pless with Abraham-Fuchs tacitly recognizes that Pless is missing a claim element, namely that the target signal includes a previously detected signal indicative of activity that precedes a neurological event. Abraham-Fuchs likewise is without such a teaching. It instead discloses comparing an incoming signal with a stored signal pattern called a template. The reference does not, however, disclose that the template includes a previously detected signal indicative of activity *preceding* a neurological event.

In fact, Abraham-Fuchs teaches that the template does *not* include a signal indicative of activity preceding a neurological event. The Abraham-Fuchs arrangement only recognizes certain signal portions associated with particular neurological activity, the pathological significance of which is unclear. (See Abraham-Fuchs at 6:23-28.) The system defines signal templates as particular portions of a signal that include markedly different waveforms or “spike-wave complexes.” (Id. at 6:23-36.) The system defines a template as a particular portion of a signal containing that marked difference in activity. Abraham-Fuchs does not teach that the template is a signal that *precedes* the activity. For example, Fig. 2 of Abraham-Fuchs shows a template that includes the shaded portion corresponding to a markedly different signal than signals that precede and follow S2 and S3. The S2-S3 complex is therefore chosen as a template, without the preceding signal S1. (Id. at 6:23-32.) Thus, the signal template disclosed in

Abraham-Fuchs, which is simply portions of a signal that differ markedly from preceding and following signals, does not constitute a target signal that includes one or more previously detected signals indicative of activity that precedes a neurological event.

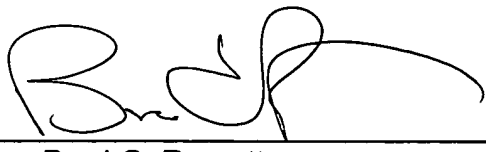
In response to these arguments, the Examiner states that "Abraham-Fuchs was relied upon merely for the teaching of target signals that are based on previous patient data or activity." (Advisory Action at 3.) Even accepting, *arguendo*, that the reference includes such a teaching, "previous patient data or activity" is not disclosure of a signal indicative of the activity that precedes a neurological event. The Examiner's admission concedes that the Abraham-Fuchs signal template does not include a previously detected signal indicative of activity that precedes a neurological event. Since Pless also does not disclose such a target signal, the combination does not suggest every element of claims 1 or 64, and the Section 103(a) rejection should be withdrawn.

Please grant any extensions of time required to enter this Brief and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: 
Brad C. Rametta
Reg. No. 54,387